



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/614,790	07/12/2000	Sharon F. Kleyne	HME/7982.001	2570
29085 7590 02/26/2008 HOWARD EISENBERG, ESQ. 1220 LIMBERLOST LANE GLADWYNE, PA 19035				
EXAMINER				
WANG, SHENGJUN				
ART UNIT		PAPER NUMBER		
1617				
MAIL DATE		DELIVERY MODE		
02/26/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SHARON F. KLEYNE

Appeal 2007-0945
Application 09/614,790
Technology Center 1600

Decided: February 26, 2008

Before, DONALD E. ADAMS, DEMETRA J. MILLS, and
LORA M. GREEN, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134.¹ The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We reverse the obviousness rejection and enter two new grounds of rejection.

Claim 90 is representative.

90. A method for moisturizing the eye comprising spraying a mist consisting essentially of droplets of water having an average diameter between 5 and 150 microns on the surface of the eye of a subject in need

¹ Oral Hearing held February 12, 2008.

thereof, wherein the amount of water that is sprayed on the eye is sufficient to hydrate the aqueous layer of the tear film on the eye of the subject but is below that which will wash away the tear film, and wherein the mist is sprayed from a device comprising a sealed container, water within said container, and an actuator for spraying a mist of water from said container, and wherein the water is sprayed on the surface of the eye within a period of 10 seconds.

Cited References

Hutson	US 5,588,564	Dec. 31, 1996
Junkel	US 5,620,633	Apr. 15, 1997
Hahn	US 5,893,515	Apr. 13, 1999
Embleton	WO 97/23177	Jul. 3, 1997

Grounds of Rejection

Claims 90-93 and 97-101 stand rejected under 35 U.S.C. § 103 as obvious over Junkel in view of Hahn, Hutson and Embleton.

DISCUSSION

Background

The present invention relates to application of therapeutic and other fluids for moisturizing and treating the surface of the eye. (Specification 1.) The surface of the eye is kept moist by the presence of tear film. (Specification 1.) The tear film has a trilaminar structure including an inner mucous layer, a middle aqueous layer and an outer lipid layer. (Specification 1-2.)

Among other features, Appellant claims a method of moisturizing the eye with an amount of water sufficient to hydrate the aqueous layer of the eye but below that which will wash away the tear film.

Obviousness

Claims 90-93 and 97-101 stand rejected under 35 U.S.C. § 103 as obvious over Junkel in view of Hahn, Hutson and Embleton.

While we find the Examiner has cited references pertinent to the claimed subject matter we disagree with the Examiner's reasoning and analysis for combining the cited references. For this reason we reverse the obviousness rejection before us and enter the following two new grounds of rejection under 37 C.F.R. § 41.50(b).

New Grounds of Rejection

Claims 90-93 and 97-101 are newly rejected under 35 U.S.C. § 102(b) as obvious over Junkel.

As to claim 90, Junkel describes a portable misting device with a fan for atomizing a liquid mist, such as water, which may be used by sunbathers and athletes as a cooling device. (Junkel, col. 1, ll. 5-19.) As is customary such devices are used to fan and cool the body, including the face. The mist is sprayed from a sealed container, such as a container sealed with a screw cap. (Junkel, col. 3, ll. 29-37.) On this record there is no evidence that a person of ordinary skill in the art using the device of Junkel's misting device would not administer a mist to the face, including the eyes for a period of time within 10 seconds.

Appellant's burden under the circumstances presented herein was described in *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) as follows:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an

applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on ‘inherency’ under 35 U.S.C. § 102, on ‘prima facie obviousness’ under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO’s inability to manufacture products or to obtain and compare prior art products [footnote omitted].

Thus, because both the device of Junkel and the claimed device are the same or substantially the same in that they provide a method of delivering a mist to the face, including the eyes, Appellant has the burden of proving that the method and mist provided by the device of Junkel produces a droplet size different from that claimed and that the mist droplets of Junkel which will wash away the tear film as opposed to hydrating the aqueous layer of the eye.

Appellant argues that Junkel does not disclose moisturizing the surface of the eye but rather pertains to cooling the body. (Br. 10.) However, on this record there is no evidence that a person of ordinary skill in the art using Junkel’s misting device would not inherently administer a mist to the face, including the eyes for a period of time within 10 seconds. Appellant argues that there is no disclosure in Junkel to administer an amount of fluid to the eye less than that which would flood the eye and wash away the tear film. (Reply Br. 3.) In response, there is no disclosure in Junkel that the amount of fluid in the mist would necessarily wash away the tear film. Thus it remains the burden of Appellant under the principles set forth in *In re Best* to show that the misting device of Junkel necessarily

provides an amount of fluid which would flood the eye. Therefore we are not persuaded by Appellant's arguments with respect to Junkel.

Therefore, we enter the above new ground of rejection of the claims for anticipation.

Claims 90-93 and 97-101 are newly rejected under 35 U.S.C. § 103(a) as obvious over Embleton in view of Hahn and Hutson.

Embleton discloses an ophthalmic treatment liquid in the form of a jet or stream. (Embleton abstract.) Embleton discloses that one of the ophthalmic treatment therapies which may be administered is water. (Embleton 13: 6-12.) Embleton further discloses that the total volume of treatment fluid is preferably no greater than 10 μ l and most preferably in the range of 3 to 8 μ l. (Embleton 3: 35-37.) Embleton does not specifically disclose administering water in the form of a mist.

Hutson discloses that administration of an ophthalmic liquid in a fluid mist to the surface of the eye. (Hutson, col. 2, ll. 5-7.) The spray mist includes an atomizer, a micromizer or an aerosol dispenser. (Hutson, col. 3, ll. 49-56.) The fluid mist dispenser of Hutson may include an eye wash solution reservoir (Hutson, col. 6, ll. 41-43) and is useful for the treatment of dry eye syndrome which requires frequent eye hydration. (Hutson, col. 6, ll. 65-67.)

Similarly, Hahn discloses a device for generating a spray mist or fine droplets to the eye. (Hahn, abstract and col. 2, ll. 41-45.) Hahn discloses that it is known to use saline solution, eye wash or eye

moistening liquids in the eye. (Hahn col. 1, ll. 25-30, 50-54.) The mist generator of Hahn can adjust the volume of the fluid pumped with each depression. (Hahn, col. 17, ll. 47-50.)

In making an obviousness determination over a combination of prior art references, it is important to identify a reason why persons of ordinary skill in the art would have attempted to make the claimed subject matter. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). If a technique has been used to improve one device, and a person of ordinary skill would recognize that it would be used in similar devices in the same way, using the technique is obvious unless its application is beyond that person's skill. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious” the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007).

We find that it would have been obvious to one of ordinary skill in the art to substitute water administered in a dose of 3 to 8 µl in the form of a jet or stream described by Embleton with administration of water in the form of a mist using a misting device for administration to the eye, as disclosed by Hutson and Hahn as they are both techniques for administration of fluids to the eye to moisturize the eye.

Appellant puts forth several Declarations from persons of ordinary skill in the art arguing unexpected results and that a long

standing unresolved problem was solved by the claimed method.
(Reply Br. 7-8.)

Appellant puts forth the Declaration of Dr. Philip Paden who testified that the misting device of the invention is a departure from previous accepted doctrine in ophthalmology. (Br. 16; Paden Declaration ¶¶ 4.)

Appellant argues the Declaration of Dr. William Mathers evidences unexpected advantages of the claimed invention which overcomes the difficulty in administering eye drops and the lack of patient compliance in administering eye drops. (Br. 16; Mathers Declaration ¶¶ 6-7.)

The Declaration of Dr. Darwin Liao indicates outstanding results with a product according to the claimed invention in the treatment of dry eye, particularly in treating patients with motor difficulties. (Br. 16; Liao Declaration ¶¶ 5-6.)

Appellant puts forth the Declaration of Dr. Rachel Garrett (Dec. 18, 2001) as evidence that a person of ordinary skill in the art would not construe Embleton as administering water to the eye but administering a treatment fluid based on water. (Br. 14-15; Garrett Declaration ¶¶ 4-5.) A second Declaration of Dr. Garrett (also dated Dec. 18, 2001) argues that eye irrigation fluids such as disclosed in Embleton require more than 3 microliters of fluid. (Garrett Declaration ¶¶ 3-4.)

We are not persuaded by the Declarations before us. In response to the Paden and Garrett Declarations, Embleton discloses that one of the

ophthalmic treatment therapies which may be administered is water. (Embleton 13: 6-12.) Embleton further discloses that the total volume of treatment fluid is preferably no greater than 10 μ l and most preferably in the range of 3 to 8 μ l (Embleton 3: 35-37) within the range of the second Garrett Declaration. Furthermore, the preponderance of evidence on this record supports a finding that a person of ordinary skill in this art would have reasonably expected that the substitution of Embleton's jet or spray with a mist, as taught by Hutson and Hahn, would moisturize the eye. With respect to the Mathers and Liao Declarations, we find one of ordinary skill in the art would have expected that substituting a jet spray with a mist would provide advantages over administration of eye drops, particularly for those with motor difficulties. It is particularly noted that Hutson provides that a mist is easier to administer than eye drops for people with neuromuscular problems (Hutson, col. 1, ll. 33-41). Therefore, we do not find the assertions made in the Paden, Mathers, Liao, or either Garrett Declarations persuasive. "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535, 538 (CCPA 1967).

Therefore, we enter the above new ground of rejection of the claims for obviousness.

SUMMARY

The obviousness rejection presented in the Answer is reversed. We enter two new grounds of rejection of the claims for anticipation and obviousness.

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner. . . .

(2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

REVERSED and 41.50(b)

Appeal 2007-0945
Application 09/614,790

Ssc:

HOWARD EISENBERG, ESQ.
1220 LIMBERLOST LANE
GLADWYNE, PA 19035